



NUCLEAR REGULATORY COMMISSION

[NRC-2014-0210]

Regulatory Guide 8.11, Revision 1, Applications of Bioassay for Uranium

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 1 to Regulatory Guide (RG) 8.11, “Applications of Bioassay for Uranium.” This guide provides methods that the NRC staff considers acceptable for the development and implementation of a bioassay program for monitoring the intake of mixtures of uranium isotopes by occupationally exposed workers. This guide applies to licenses issued under “Domestic Licensing of Special Nuclear Material.”

ADDRESSES: Please refer to Docket ID NRC-2014-0210 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using any of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2014-0210**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Document collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “[ADAMS Public Documents](#)” and then select “[Begin Web-based ADAMS Search](#).” For problems with ADAMS,

please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdresource@nrc.gov. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. Revision 1 of RG 8.11 is available in ADAMS under Accession No. ML15054A618. The regulatory analysis may be found in ADAMS under Accession No. ML14133A612.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is issuing a revision to an existing guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and data that the staff needs in its review of applications for permits and licenses, or for amendments to such permits and licenses. The draft Revision 1 of RG 8.11 was issued with a temporary identification as Draft Regulatory Guide, DG-8054 and published in the *Federal Register* to obtain public comments (79 FR 60190; October 6, 2014).

The NRC issued the initial version of RG 8.11 in June 1974 to provide guidance to NRC licensees on methods the staff found acceptable to demonstrate compliance with the then current version of NRC's radiation protection regulations in 10 CFR part 20. In 1991 the NRC promulgated amendments to its 10 CFR part 20 regulations (56 FR 23360; May 21, 1991). The 1991 rulemaking included substantive amendments to the 10 CFR part 20 regulations as well as a renumbering of those regulations. As such, this revision (Revision 1) to the guide updates the guide's cross-references to the current 10 CFR part 20 regulations.

In addition, the guide endorses for use certain sections of a voluntary consensus standard, namely, the American National Standards Institute/Health Physics Society N13.22-2013 standard, "Bioassay Programs for Uranium," as a means for licensees to demonstrate compliance with the NRC regulations, 10 CFR 20.1201, "Occupational Dose Limits for Adults," and 10 CFR 20.1204, "Determination of Internal Exposure." Specifically, 10 CFR 20.1201(e) requires NRC licensees to limit the soluble uranium intake to an occupational worker to 10 milligrams in a week, in addition to annual occupational dose limits, and 10 CFR 20.1204(a) requires NRC licensees to take suitable and timely measurements of the concentrations of radioactive materials in air in work areas and the quantities of radionuclides in the bodies of occupational workers. Finally, this guide identifies the bioassay interpretation

methods in the NRC document NUREG/CR-4884, "Interpretation of Bioassay Measurement," as an acceptable method to comply with NRC requirements.

II. Additional Information

DG-8054 was published in the *Federal Register* (79 FR 60190; October 6, 2014) for a 60-day public comment period. The public comment period closed on December 5, 2014. The NRC received one comment submission. This comment submission and the staff responses to the comments set forth in that comment submission are available under ADAMS Accession Number ML15014A269.

III. Congressional Review Act

This regulatory guide is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting

Licensees may voluntarily use the guidance in this regulatory guide (Revision 1 of RG 8.11) to demonstrate compliance with the underlying NRC regulations. Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations. Current licensees (i.e., persons holding a NRC issued license as of the date of issuance of this regulatory guide) may continue to use guidance the NRC found acceptable for complying with the identified regulations

as long as their current licensing basis remains unchanged. The acceptable guidance may be from the previous version of this regulatory guide. Licensees may use the information in this regulatory guide for actions which do not require NRC review and approval. Licensees may also use the information in this regulatory guide to resolve regulatory or inspection issues.

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide (see 10 CFR 70.76, "Backfitting"). The NRC staff does not expect any current licensee to use or commit to using the guidance in this regulatory guide, unless such licensee makes a change to its licensing basis. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this regulatory guide. Examples of such regulatory actions include the issuance of an order or generic communication, or the promulgation of a rule, requiring the use of this regulatory guide without further backfit consideration.

During regulatory discussions on licensee-specific operational issues, the NRC staff may discuss with licensees various actions consistent with staff positions in this regulatory guide, as one acceptable means of meeting the underlying NRC regulatory requirements. Such discussions would not ordinarily be considered backfitting, even if prior versions of this regulatory guide are part of the licensee's licensing basis. However, unless this regulatory guide is part of the licensee's licensing basis, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If a current licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, then the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory

requirements. Such a request by the NRC staff is not considered backfitting as defined in 10 CFR 70.76(a)(1).

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in the Implementation section of this regulatory guide, then the licensee may file a backfit appeal with the NRC in accordance with the guidance in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" and NUREG-1409, "Backfitting Guidelines."

Dated at Rockville, Maryland, this 8th day of July, 2015.

For the Nuclear Regulatory Commission.

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